

REMARKS

Upon entry of the present amendment, claims 1-27 are pending in the instant application. Claims 1, 4, 6, 7, 9, 11, 13 and 15 have been amended. Support for the claim amendments presented herein is found throughout the specification and in the claims as originally filed. For example, support for the rigid polymer compositions and/or rigid polymer vehicles recited by amended claims 1, 4, 6, 7, 9 11, 13 and 15 is found at least at page 8, line 27 through page 9, line 10. Accordingly, no new matter has been added the amendments presented herein.

Double Patenting

Claims 1-5, 7, 15-21, 23 and 27 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,712,610 ("the '610 patent").

In conjunction with the response filed July 26, 2005, Applicants previously submitted a terminal disclaimer over the '610 patent, along with the appropriate fee. The Examiner has indicated that the July 26, 2005 terminal disclaimer has not been accepted because "an attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34". (Office Action, page 2).

Applicants request reconsideration of the rejection of the July 26, 2005 terminal disclaimer and submit that this disclaimer was signed by an attorney of record in this case. The instant application is a continuation of U.S. Application No. 09/963,880, now issued as U.S. Patent No. 6,712,610. In the "Request for Filing a New Nonprovisional Application Under 37 C.F.R. § 1.53(b)" submitted on March 29, 2004, Applicants included a copy of the declaration/power of attorney signed by the named inventors, as well as a copy of the Revocation by Assignee and New Power of Attorney, which were filed in the parent application (*i.e.*, U.S. Application No. 09/963,880). The Revocation by Assignee and New Power of Attorney filed on February 3, 2003 appointed all attorneys and agents associated with Customer No. 30623, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., including the undersigned (Ingrid A. Beattie, Reg. No. 42,306), who signed the terminal disclaimer filed on July 26, 2005. Applicants enclose herewith a copy of the following documents as evidence that the undersigned is an attorney of record in the instant application:

- Copy of the Request for Filing a New Nonprovisional Application Under 37 C.F.R. § 1.53(b), which lists all papers filed on March 29, 2004, including the Declaration and Power of Attorney from Parent Application 09/963,880 and the Revocation by Assignee and New Power of Attorney from Parent Application 09/963,880
- Copies of the Declaration and Supplemental Declarations filed U.S. Application No. 09/963,880
- Copy of the Revocation of Powers of Attorney and Appointment of New Attorneys and/or Agents filed in U.S. Application No. 09/963,880
- Copy of the Express Mail Label No. EV328182377US, date stamped March 29, 2004
- Copy of the return postcard received from the USPTO, which acknowledges receipt of all papers filed on March 29, 2004, including the signed Declaration (copy, 3 counterparts) and the Revocation by Assignee and New Power (copy, 11 pages)

Thus, Applicants respectfully submit that the change in power of attorney during the prosecution of parent application 09/963,880 was properly identified in the instant continuation application in compliance with the provisions of 37 C.F.R. § 1.63(d)(4). Accordingly, the July 26, 2005 terminal disclaimer was signed by an attorney of record in the instant application in accordance with the requirements of 37 CFR 1.34. Applicants request, therefore, that the Examiner accept the terminal disclaimer that was previously filed on July 26, 2005 along with the appropriate fees and withdraw the double-patenting rejection.

Claim Objections

Claims 9 and 13 have been objected to because of informalities contained therein. In particular, the Examiner has objected to the terms “the antibiotic” in claim 9 and “the treatment site” in claim 13 as lacking sufficient antecedent basis.

Claims 9 and 13 have been amended to maintain antecedent basis throughout the claims. Accordingly, withdrawal of these objections is requested.

Claim Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1-27 have been rejected under 35 U.S.C. §112, first paragraph as lacking written description. According to the Examiner, the specification does not disclose “a rigid copolymer vehicle nor rigid copolymer”.

Applicants traverse. The pending claims, including independent claims 1, 6, 7, 9, 11 and 13, have been amended to recite a “rigid polymer composition” and/or a “rigid polymer vehicle”. Such rigid polymer compositions and vehicles are described throughout the as-filed specification. For example, at page 8, line 27 through page 9, line 10, the specification teaches that the polymers of the claimed invention are selected to have a level of rigidity required to accomplish the aseptic placement of the endodontic fiber within a root canal. Moreover, the specification provides examples of polymer compositions and polymer vehicles that have been sprayed with a biocompatible refrigerant spray to increase the rigidity of those endodontic fibers. Thus, the claim terms are literally supported by the as-filed specification.

In addition, the skilled artisan would understand that the plain meaning of the term “rigid” is “not bending or flexible; stiff and hard”. *See e.g.*, Webster’s New World College Dictionary, 3rd Ed., 1996, copy enclosed herewith). As such, Applicants submit that the claimed subject matter was described in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the instant application was filed.

For each claimed genus, the Examiner must determine whether there is sufficient written description to inform a skilled artisan that Applicant was in possession of the claimed genus at the time the application was filed. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by relevant identifying characteristics, *i.e.*, structure or other physical and/or chemical characteristics, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In this case, the specification provided more than a representative number of examples of the structural, physical, and chemical characteristics of a rigid polymer composition of an endodontic fiber. For example, on page 4, lines 1-4, the specification describes fibers containing less than 20%, less than 15%, less than 10%, about 9.3%. To further define the correlation between function and structure, the specification states

that the fiber has rigidity similar to that of gutta-percha, a naturally-occurring polymer that is rigid at room temperature. (See specification at page 17, lines 14-16). In addition to chemically regulating the rigidity by lowering the percentage of polymer compared to earlier flexible, tacky fibers, the specification also states that the rigidity can also be increased by spraying the polymer with a refrigerant spray to increase its stiffness. (See specification at page 13, lines 21-24). One of skill in the art would have no difficulty in understanding how to make a rigid fiber compared to a flexible fiber and the process for manipulating rigidity is entirely predictable. Thus, Applicants submit that there is sufficient written description to inform a skilled artisan that Applicants was in possession of the claimed genus at the time the application was filed.

Accordingly, this rejection should be withdrawn.

Claim Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1-27 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite. According to the Examiner, the terms “rigid copolymer vehicle” and “rigid copolymer” are unclear.

As described above, the pending claims have been amended to recite a “rigid polymer composition” and/or a “rigid polymer vehicle”. Applicants submit that these claim terms are clear and particularly points out the claimed subject-matter which Applicants regard as their invention. As described above, the term “rigid” has a plain meaning that is particular and distinct. Thus, one of ordinary skill in the art would understand that the terms “rigid polymer” and/or “rigid polymer vehicle” signify polymers and vehicles that are devoid or deficient in flexibility. Accordingly, Applicants request that the Examiner withdraw this rejection.

Claim Rejections Under 35 U.S.C. §102(b)

Claims 1-3, 5, 21 and 22 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,892,736 by Goodson (“Goodson”). According to the Examiner, Goodson describes a “fiber comprising a copolymer vehicle having incorporated therein one or more medicaments”. (Office Action, page 4).

Independent claim 1 has been amended to recite an endodontic fiber suitable for the local delivery and sustained release of one or more medicaments incorporated therein to an intracanal treatment site, wherein the fiber comprises a rigid polymer vehicle having incorporated therein

one or more medicaments, wherein the fiber has a size and shape suitable for placement in a root canal.

Independent claim 6, as amended, is directed to a modified periodontal fiber suitable for the delivery and sustained release of medicament incorporated therein to an intracanal treatment site, wherein the fiber comprises a rigid polymer vehicle having incorporated therein one or more medicaments, wherein the polymer is treated to decrease its surface tackiness and wherein the fiber has a size and shape suitable for placement in a root canal.

Thus, these amended claims and their respective dependent claims (including claims 2-3, 5, 21 and 22) are directed to rigid fibers having one or more medicaments incorporated therein.

Goodson, in contrast, does not disclose or suggest rigid fibers. Goodson explicitly states that the fibers described therein must be “sufficiently flexible and formable to conform readily to the periodontal site to be treated”, *i.e.*, these fibers are soft enough to bend around the perimeter of a tooth to make contact with the gum tissue to be treated. (See Goodson at col. 3, lines 32-33). Accordingly, this reference does not disclose every element of the rigid fibers recited by amended claims 1-3, 5, 6, 21 and 22. As such, the claimed rigid fibers are not anticipated by the teachings of Goodson, and this rejection should be withdrawn.

Claim Rejections Under 35 U.S.C. §103(a)

Claim 4

Claim 4 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Goodson in view of U.S. Patent No. 5,114,718 by Damani (“Damani”). According to the Examiner, “it would have been obvious to one having ordinary skill in the art to incorporate medicament of clindamycin to the fiber of Goodson, since Damani discloses both as known antibiotics”. (Office Action, page 5).

Claim 4 depends independent claim 1 and, therefore, contains all of the limitations recited by amended claim 1. As described above, claim 1 has been amended to recite an endodontic fiber suitable for the local delivery and sustained release of one or more medicaments incorporated therein to an intracanal treatment site, wherein the fiber comprises a rigid polymer vehicle having incorporated therein one or more medicaments, wherein the fiber has a size and shape suitable for placement in a root canal. Thus, claim 4 is also directed to rigid fibers.

As described above, the Goodson reference does not teach or suggest a rigid fiber. Moreover, the addition of the Damani reference fails to cure the deficiencies in the teachings of Goodson, as Damani does not describe or suggest a rigid fiber. In contrast to the rigid fiber recited by claim 4, the fibers described by Damani are “flexible and solid”. (See Damani at col. 2, lines 29-31). Thus, Goodson and Damani, alone or in combination, do not teach or suggest a rigid fiber. Accordingly, these references do not render the fibers of the claimed invention obvious. Withdrawal of this rejection is requested.

Claims 7-14 and 23-26

The Examiner has rejected claims 7-14 and 23-26 as being unpatentable over Goodson. According to the Examiner, “one skilled in the art would recognize that the fiber of Goodson is of a size and characteristics sufficient for positioning in a root canal and Goodson shows methods method of localized treatment with the oral cavity.” (Office Action, page 5).

Claim 7 has been amended to recite a method for the local delivery and sustained release of a medicament to an intracanal treatment site by (a) obtaining an endodontic fiber suitable for intracanal use having one or more medicaments incorporated therein, wherein said endodontic fiber comprises a rigid polymer; (b) positioning the fiber of (a) in the root canal such that the fiber is in direct contact with the treatment site; and (c) maintaining the fiber at the treatment site, wherein the medicament is delivered to the treatment site at a controlled rate.

As amended, claim 9 is directed to a method of treating an endodontic bacterial infection comprising the steps of (a) obtaining an endodontic fiber suitable for intracanal use having one or more medicaments incorporated therein, wherein said endodontic fiber comprises a rigid polymer; (b) inserting the fiber of (a) into a root canal such that the fiber is in direct contact with a treatment site in the root canal; and (c) maintaining the fiber at the treatment site, wherein the antibiotic is delivered to the treatment site.

Amended claim 11 recites a method of disinfecting a root canal receiving endodontic treatment by (a) obtaining an endodontic fiber suitable for intracanal use having one or more medicaments incorporated therein, wherein said endodontic fiber comprises a rigid polymer; (b) inserting the fiber of (a) into a debrided and irrigated root canal such that the fiber is in direct contact with a treatment site in the root canal; and (c) maintaining the fiber at the treatment site, wherein the medicament is administered to the treatment site at a controlled rate.

Claim 13 has been amended to recited a method of reducing inflammation in periapical tissue of a tooth undergoing endodontic treatment by (a) obtaining an endodontic fiber suitable for intracanal use having incorporated therein an anti-inflammatory agent, wherein said endodontic fiber comprises a rigid polymer; (b) positioning the fiber into a debrided and irrigated root canal such that the fiber is in direct contact with an inflamed tissue in the root canal; and (c) maintaining the endodontic fiber at the treatment site, wherein the anti-inflammatory agent is delivered to the site of inflammation.

Thus, these methods and their respective dependent claims (including claims 8, 10, 12 and 23-26) recite the use of a rigid fiber. As described above, Goodson does not disclose or suggest rigid fibers or methods of using rigid fibers. Moreover, the fibers described by Goodson must be “sufficiently flexible and formable to conform readily to the periodontal site to be treated”, *i.e.*, the flexible fiber is soft enough to wrap around the unique geometry of the perimeter of an individual’s tooth to ensure contact with the gum tissue to be treated. (*See* Goodson at col. 3, lines 32-33). Thus, Goodson explicitly teaches away from the use of a rigid fiber, and, therefore, a person of ordinary skill in the art would have no motivation from the teachings of Goodson to modify the fibers described therein to generate rigid fibers. As such, the methods of the claimed invention are not obvious over the teachings of the Goodson reference, and this rejection should be withdrawn.

Claims 15-20 and 27

Claims 15-20 and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Goodson in view of U.S. Patent No. 4,003,810 by Hoyt et al. (“Hoyt”). According to the Examiner, it would have been “an obvious matter of choice to one of ordinary skill in the art as to the specific amount of a known material and as to its intended use”. (Office Action, page 6).

Applicants traverse this rejection on the grounds that the Examiner has failed to establish a *prima facie* case of obviousness. A *prima facie* case of obviousness requires some suggestion or motivation, either in the references themselves or in the knowledge generally available in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 706.02(j).

Claims 15-20 and 27 depend, directly or indirectly, from independent claim 1 and, therefore, contain all of the limitations recited by amended claim 1. As described above, claim 1 has been amended to recite an endodontic fiber suitable for the local delivery and sustained release of one or more medicaments incorporated therein to an intracanal treatment site, wherein the fiber comprises a rigid polymer vehicle having incorporated therein one or more medicaments, wherein the fiber has a size and shape suitable for placement in a root canal. Thus, claims 15-20 and 27 are also directed to rigid fibers having one or more medicaments incorporated therein, wherein the fiber comprises an ethylene vinyl acetate copolymer comprising less than 20% vinyl acetate by weight.

As described above, Goodson does not disclose or suggest rigid fibers or methods of using rigid fibers. Moreover, this reference does not disclose or suggest fibers that comprise an ethylene vinyl acetate copolymer having less than 20% vinyl acetate by weight. In contrast to the fibers recited by claims 15-20 and 27, the Goodson fibers contain 45% vinyl acetate by weight. As Goodson explicitly requires that the fibers are “sufficiently flexible and formable to conform readily to the periodontal site to be treated” (col. 3, lines 32-33), a person of ordinary skill in the art would not have been motivated by the teachings of Goodson to modify the fibers described therein to produce rigid fibers. Thus, one of ordinary skill in the art would have no motivation to combine the Goodson fibers with the fibers described in the Hoyt reference.

The fact that references can be combined or modified does not render the resulting combination obvious unless the prior art also suggests the desirability of the combination. (See MPEP §2143.01, citing *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)). However, there is no suggestion in the Goodson reference that would motivate a skilled artisan to modify the fibers described therein to contain less than 20% EVA to produce a rigid fiber. Thus, the fact that the Goodson and Hoyt references can be combined is not sufficient to establish a *prima facie* case of obviousness.

Moreover, an assertion that modifying the Goodson reference would have been within the ordinary skill of the art at the time the claimed invention was made because the cited references were individually known in the art at the time the instant application was filed is also insufficient to establish a *prima facie* case of obviousness without some objective reason to combine the references. (See MPEP §2143.01, citing *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pate. App. & Inter. 1993)). Thus, the fact that the Goodson and Hoyt references were known in the art

individually at the time the instant application was filed does not render the claimed fibers obvious, as there is no teaching or suggestion in the Goodson reference that would motivate one of ordinary skill in the art to modify the fibers described therein.

Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, and this rejection should be withdrawn.

CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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*Dedicated
to David B. Guralnik
lexicographical mentor and friend*

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ME *rihtwis* < OE: see **RIGHT** & **-WISE**] 1. acting in a just, upright manner; doing what is right; virtuous [a righteous man] 2. morally justifiable [a righteous cause]

Rijeka (rĕ yek'ə) seaport in W Croatia, on the Adriatic; pop.

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amount) on a cash register.

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Date of Deposit: March 29, 2004

Attorney Docket No. 25669-014 CIP CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

FIRST-NAMED INVENTOR OR Mario Abdenmour et al.
APPLICATION IDENTIFIER:

FOR: CHARACTERIZATION OF AN ANTIBIOTIC IMPREGNATED
 DELIVERY SYSTEM AS AN INTRACANAL MEDICAMENT IN
 ENDODONTIC THERAPY

MAIL STOP PATENT APPLICATION

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

**REQUEST FOR FILING A NEW NONPROVISIONAL APPLICATION
UNDER 37 C.F.R. §1.53(b)**

1. This is a request for filing a continuation patent application under 37 C.F.R. §1.53(b).
 This application is a continuation of USSN 09/963,880, filed September 26, 2001, which claims
 priority of 60/240,004, filed October 12, 2000, and is a continuation-in-part of USSN
 009/540,088, filed March 31, 2000, which claims priority to USSN 60/127,497, filed April 2,
 1999 and Foreign Application No. CA 2343471, filed March 30, 2001.
2. Specification and Drawings (Total pages: 35);
 Specification (21 pages); Claims (3 pages); Abstract (1 page); and
 Drawings: 10 sheets (Figures 1 – 10)

 ☒ Formal
3. Declaration and Power of Attorney
 (Copy from Parent Application 09/963,880) (3 counterparts, 3 pages, total of 9 pages)

 ☒ Signed
4. Revocation By Assignee And New Power of Attorney
 (Copy from Parent Application 09/963,880) (11 pages)
5. Information Disclosure Statement Form PTO-1449
 (Copy from Parent Application 09/963,880) (3 pages)

EV328182377US

U.S.S.N.: TBA
Filed: March 29, 2004

6. Fee Calculation

CLAIMS AS FILED					
Claims	Number Filed	Basic Fee Allowance	Number Extra	Rate	Basic Fee 37 C.F.R. 1.16(a) \$ 770.00
Total Claims (37 C.F.R. 1.16(c))	20	- 20 =	0	\$18.00	\$ 0
Independent Claims (37 C.F.R. 1.16(b))	7	- 3 =	4	\$86.00	\$ 344.00
Multiple Dependent Claim(s), if any (37 C.F.R. 1.16(d))	0			\$290.00	\$ 0
SUBTOTAL:					\$1,114.00
Reduction by 50% for filing by small entity:					\$ 557.00
TOTAL FEE:					\$ 557.00

7. A check (#18367) in the amount of \$557.00 is enclosed. The Commissioner is authorized to charge any additional fees due, or credit overpayments, to Deposit Account No. 50-0311, Ref. No. 25669-014 CIP CON.


8. The Commissioner is hereby authorized to credit overpayments or charge the following fees to Deposit Account No. 50-0311, Ref. No. 24299-508-CON3:

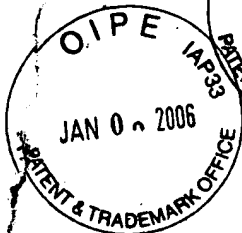
Fees required under 37 C.F.R. §1.16;
Fees required under 37 C.F.R. §1.17;
Fees required under 37 C.F.R. §1.18.

9. Return Receipt Postcard Enclosed.

Respectfully submitted,

Dated: March 29, 2004


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DOCKET NO. 1564.2002-003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Supplemental Declaration for Patent Application

As a named inventor, I hereby declare that:

My residence, mailing address and citizenship are as stated next to my name;

I believe I am the original, first and sole inventor (if only one name is listed) or an original, first and joint inventor (if plural names are listed in the signatory page(s) commencing at page 3 hereof) of the subject matter which is claimed and for which a patent is sought on the invention entitled

Characterization of an Antibiotic Impregnated Delivery System as an Intracanal Medicament in Endodontic Therapy

the specification of which (check one)

☐ is attached hereto.

☒ was filed on September 26, 2001 as United States Application

Number No. 09/963,880

and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

<u>Prior Foreign Application(s)</u>			Priority Not Claimed	Certified Copy Filed?	
				YES	NO
<u>2343471</u> (Number)	<u>Canada</u> (Country)	<u>30 March 2001</u> (Day/Month/Year filed)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

<u>60/240,004</u> (Application Number)	<u>October 12, 2000</u> (Filing Date)
_____ (Application Number)	_____ (Filing Date)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Declaration for Patent Application

As a named inventor, I hereby declare that:

My residence, mailing address and citizenship are as stated next to my name;

I believe I am the original, first and sole inventor (if only one name is listed) or an original, first and joint inventor (if plural names are listed in the signatory page(s) commencing at page 3 hereof) of the subject matter which is claimed and for which a patent is sought on the invention entitled

Characterization of an Antibiotic Impregnated Delivery System as an Intracanal Medicament in Endodontic Therapy

the specification of which (check one)

☐ is attached hereto.

☒ was filed on September 26, 2001 as United States Application

Number No. 09/963,880

and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

<u>Prior Foreign Application(s)</u>			Priority Not Claimed	Certified Copy Filed?	
				YES	NO
<u>2343471</u>	<u>Canada</u>	<u>30 March 2001</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
(Number)	(Country)	(Day/Month/Year filed)			
<u> </u>	<u> </u>	<u> </u>			
(Number)	(Country)	(Day/Month/Year filed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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(Number)	(Country)	(Day/Month/Year filed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

60/240,004
(Application Number)

October 12, 2000
(Filing Date)

(Application Number)

(Filing Date)

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information known by me to be material to patentability as defined in 37 C.F.R. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

<u>09/540,088</u> (Application Serial No.)	<u>March 31, 2000</u> (Filing date)	<u>Pending</u> (Status: patented, pending, abandoned)
<u> </u> (Application Serial No.)	<u> </u> (Filing date)	<u> </u> (Status: patented, pending, abandoned)
<u> </u> (Application Serial No.)	<u> </u> (Filing date)	<u> </u> (Status: patented, pending, abandoned)
<u> </u> (Application Serial No.)	<u> </u> (Filing date)	<u> </u> (Status: patented, pending, abandoned)

As a named inventor, I hereby appoint the attorneys and/or agents associated with
Hamilton, Brook, Smith & Reynolds, P.C., 530 Virginia Road, P.O. Box 9133, Concord, Massachusetts 01742-9133, Customer No. 21005,

and _____,

to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Please send correspondence to:

☒ Customer No. 21005
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 Virginia Road
P.O. Box 9133
Concord, MA 01742-9133

or

☐ Address as follows:

Direct telephone calls to: Lisa M. Treannie, Esq. Telephone No.: 978-341-0036

Direct facsimiles to: Lisa M. Treannie, Esq. Facsimile No.: 978-341-0136

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole

or first inventor Mario Abdennour

Inventor's Signature  Date 1/30/2002.

Residence 12 Kippy Drive
Newton, MA 02468

Citizenship U.S.A.

Mailing Address same as above

Full name of second joint

inventor, if any Philip Stashenko

Inventor's Signature *Philip Stashenko* Date 1/23/02

Residence 10 Newport Lane

Medfield, MA 02052-1929

Citizenship U.S.A.

Mailing Address same as above

Full name of third joint

inventor, if any Michele Scrim

Inventor's Signature *Michele Scrim* Date 4/15/02

Residence 28 Princeton Drive

Manalapan, NJ

Citizenship U.S.A.

Mailing Address same as above

Full name of fourth joint

inventor, if any Jack Gilad

Inventor's Signature *Jack Gilad* Date 2-1-02

Residence 18 Glendale Road, #1

Chestnut Hill, MA 02167-02467

Citizenship Canada

Mailing Address same as above

Full name of fifth joint

inventor, if any Max Goodson

Inventor's Signature *Max Goodson* Date 1-23-02

Residence 36 Fresh Pond Place

Cambridge, MA 02138

Citizenship U.S.A.

Mailing Address same as above

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information known by me to be material to patentability as defined in 37 C.F.R. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

<u>09/540.088</u> (Application Serial No.)	<u>March 31, 2000</u> (Filing date)	<u>Pending</u> (Status: patented, pending, abandoned)
<u> </u> (Application Serial No.)	<u> </u> (Filing date)	<u> </u> (Status: patented, pending, abandoned)
<u> </u> (Application Serial No.)	<u> </u> (Filing date)	<u> </u> (Status: patented, pending, abandoned)
<u> </u> (Application Serial No.)	<u> </u> (Filing date)	<u> </u> (Status: patented, pending, abandoned)

As a named inventor, I hereby appoint the attorneys and/or agents associated with
Hamilton, Brook, Smith & Reynolds, P.C., 530 Virginia Road, P.O. Box 9133, Concord, Massachusetts 01742-9133, Customer No. 21005,

and _____,

to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Please send correspondence to:

☒ Customer No. **21005**
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 Virginia Road
P.O. Box 9133
Concord, MA 01742-9133

or

☐ Address as follows: _____

Direct telephone calls to: Lisa M. Treannie, Esq. Telephone No.: 978-341-0036

Direct facsimiles to: Lisa M. Treannie, Esq. Facsimile No.: 978-341-0136

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole

or first inventor Mario Abdenmour

Inventor's Signature _____ Date _____

Residence 12 Kippy Drive

Newton, MA 02468

Citizenship U.S.A.

Mailing Address same as above

Full name of second joint

inventor, if any Philip Stashenko

Inventor's Signature _____ Date _____

Residence 10 Newport Lane
Medfield, MA 02052-1929

Citizenship U.S.A.

Mailing Address same as above

Full name of third joint

inventor, if any Michele Scrima

Inventor's Signature _____ Date _____

Residence 28 Princeton Drive
Manalapan, NJ

Citizenship U.S.A.

Mailing Address same as above

Full name of fourth joint

inventor, if any Jack Gilad

Inventor's Signature _____ Date _____

Residence 18 Glenland Road, #1
Chestnut Hill, MA 02167

Citizenship Canada

Mailing Address same as above

Full name of fifth joint

inventor, if any J. Max Goodson

Inventor's Signature *J. Max Goodson* Date Oct. 22, 1992

Residence 576 Fresh Pond Place
Cambridge, MA 02138

Citizenship U.S.A.

Mailing Address same as above

DOCKET NO. 1564.2002-003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Supplemental Declaration for Patent Application

As a named inventor, I hereby declare that:

My residence, mailing address and citizenship are as stated next to my name;

I believe I am the original, first and sole inventor (if only one name is listed) or an original, first and joint inventor (if plural names are listed in the signatory page(s) commencing at page 3 hereof) of the subject matter which is claimed and for which a patent is sought on the invention entitled

Characterization of an Antibiotic Impregnated Delivery System as an Intracanal Medicament in Endodontic Therapy

the specification of which (check one)

- ☐ is attached hereto.
- ☒ was filed on September 26, 2001 as United States Application

Number No. 09/963,880

and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

<u>Prior Foreign Application(s)</u>			Priority Not Claimed	Certified Copy Filed? YES	NO
<u>2343471</u> (Number)	<u>Canada</u> (Country)	<u>30 March 2001</u> (Day/Month/Year filed)	[]	[]	[X]
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	[]	[]	[]
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	[]	[]	[]

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

60/240,004
(Application Number)October 12, 2000
(Filing Date)_____
(Application Number)_____
(Filing Date)

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information known by me to be material to patentability as defined in 37 C.F.R. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

<u>09/540,088</u> (Application Serial No.)	<u>March 31, 2000</u> (Filing date)	<u>Pending</u> (Status: patented, pending, abandoned)
<u> </u> (Application Serial No.)	<u> </u> (Filing date)	<u> </u> (Status: patented, pending, abandoned)
<u> </u> (Application Serial No.)	<u> </u> (Filing date)	<u> </u> (Status: patented, pending, abandoned)
<u> </u> (Application Serial No.)	<u> </u> (Filing date)	<u> </u> (Status: patented, pending, abandoned)

As a named inventor, I hereby appoint the attorneys and/or agents associated with
Hamilton, Brook, Smith & Reynolds, P.C., 530 Virginia Road, P.O. Box 9133, Concord, Massachusetts 01742-9133, Customer No. 21005,

and _____,

to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Please send correspondence to:

☒ Customer No. 21005
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 Virginia Road
P.O. Box 9133
Concord, MA 01742-9133

or

☐ Address as follows: _____

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole
or first inventor Mario Abdennour
Inventor's Signature _____ Date _____
Residence 12 Kippy Drive
Newton, MA 02468
Citizenship U.S.A.
Mailing Address same as above

Full name of second joint

inventor, if any Philip Stashenko

Inventor's Signature _____ Date _____

Residence 10 Newport Lane

Medfield, MA 02052-1929

Citizenship U.S.A.

Mailing Address same as above

Full name of third joint

inventor, if any Michele Scime

Inventor's Signature _____ Date _____

Residence 28 Princeton Drive

Manalapan, NJ

Citizenship U.S.A.

Mailing Address same as above

Full name of fourth joint

inventor, if any Jack Gilad

Inventor's Signature _____ Date 12 OCT 02

Residence 18 Glenland Road. #1

Chestnut Hill, MA 02167

Citizenship Canada

Mailing Address same as above

Full name of fifth joint

inventor, if any J. Max Goodson

Inventor's Signature _____ Date _____

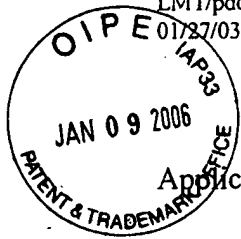
Residence 36 Fresh Pond Place

Cambridge, MA 02138

Citizenship U.S.A.

Mailing Address same as above

LMT/pdd
01/27/03



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mario Abdenmour, Philip Stashenko, Michele Scime, Jack Gilad and J. Max Goodson

Application No.: 09/963,880 Group: 3732

Filed: September 26, 2001 Examiner: Not provided

Confirmation No.: 9204

For: Characterization of an Antibiotic Impregnated Delivery System as an Intracanal Medicament in Endodontic Therapy

FILE COPY

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202	
on <u>2/3/03</u>	<u>Paula Depelteau</u>
Date	Signature
<u>PAULA DEPELTEAU</u>	
Typed or printed name of person signing certificate	

REVOCATION OF POWERS OF ATTORNEY
AND APPOINTMENT OF NEW ATTORNEYS AND/OR AGENTS

Assistant Commissioner for Patents
P.O. Box 2327
Arlington, VA 22202

Sir:

Forsyth Dental Infirmary for Children, a Corporation duly organized under the laws of the Commonwealth of Massachusetts, is the assignee of the entire right, title and interest in the above-identified application. Forsyth Dental Infirmary for Children hereby appoints the following attorneys and/or agents associated with:

Customer No. 30623
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C.
One Financial Center
Boston, MA 02111

Attorney or Agent	Registration No.	Attorney or Agent	Registration No.
Danielle T. Abramson	P-52,539	Shane Hunter	41,858
Kevin Ainsworth	39,586	David E. Johnson	41,874
Ingrid Beattie	42,306	Christina Karnakis	45,899
William Belanger	40,509	Jennifer Karnakis	P-53,097
Charles E. Bell	48,128	Kristin E. Konzak	44,848
Naomi Biswas	38,384	Cynthia Kozakiewicz	42,764
Bradford C. Blaise	47,429	Alison Marcotte	51,998
Sean M. Coughlin	48,593	Barry J. Marenberg	40,715
David F. Crosby	36,400	Scott D. Miller	43,803
Christopher J. Cuneo	42,450	A. Jason Mirabito	28,161
Brett N. Dorny	35,860	Michel Morency	50,183
Ivor R. Elrifi	39,529	Carol H. Peters	45,010
James F. Ewing	P-52,875	Matthew Pavao	50,572
Heidi A. Erlacher	45,409	Michael Renaud	44,299
Flora Feng	51,673	Robert J. Sayre	42,124
Eugene Feher	33,171	C. Eric Schulman	43,350
James G. Gatto	32,694	Gregory J. Sieczkiewicz	48,223
Richard Gervase	46,725	Eric Sinn	40,177
Matthew J. Golden	35,161	Thomas M. Sullivan	39,392
Sonia K. Guterman	44,729	Janine Susan	46,119
Melissa Handler	P-52,988	Howard Susser	33,556
Paul Hayes	28,307	Nicholas P. Triano III	36,397
Brian P. Hopkins	42,669		

to prosecute the above-identified application and any divisions or continuations thereof and to conduct all business in the United States Patent and Trademark Office. All previously granted Powers of Attorney are hereby revoked.

A Statement under 37 C.F.R. §3.73(b) is submitted herewith.

All correspondence should be sent to Ingrid A. Beattie, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C., One Financial Center, Boston, MA 02111. Please direct all telephone calls to Ingrid A. Beattie at (617) 348-1838, and all facsimile communications to (617) 542-2241.

Respectfully submitted,
Forsyth Dental Infirmary for Children

By 

Title President & CEO

Date January 30, 2003



Docket No. 1564.2002-003

STATEMENT UNDER 37 C.F.R. § 3.73(b)

Applicants: Mario Abdennour, Philip Stashenko, Michele Scrimme, Jack Gilad and J. Max Goodson

Application No.: 09/963,880 Filed: September 26, 2001

For: Characterization of an Antibiotic Impregnated Delivery System as an Intracanal Medicament in Endodontic Therapy

Forsyth Dental Infirmary for Children, a

corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is

- A. ☒ the assignee of the entire right, title and interest in the patent application identified above; or
- B. ☐ an assignee together with [] of the entire right, title and interest in the patent application identified above. A separate Statement under 37 CFR § 3.73(b) is being submitted.

The right, title and interest of the above-named assignee in the patent application identified above is established by virtue of:

- A. ☒ An assignment from the inventors of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel _____, Frames _____, or a copy thereof is attached.

OR

- B. ☐ A chain of title from the inventor(s) of the patent application identified above, to the current assignee as shown below:

1. From: _____ To: _____
The document was recorded in the Patent and Trademark Office at
Reel _____, Frame _____, or a copy thereof is attached.
2. From: _____ To: _____
The document was recorded in the Patent and Trademark Office at
Reel _____, Frame _____, or a copy thereof is attached.
3. From: _____ To: _____
The document was recorded in the Patent and Trademark Office at
Reel _____, Frame _____, or a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Date: 1/30/03

Name: Richard L. Pharo, Sc.D.

Title: Executive Vice President

Signature: Richard L. Pharo



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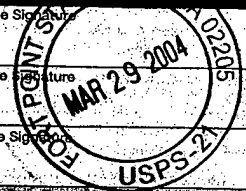
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MINTZ LEVIN COHN FERRIS
GLOVSKY & POPE PC
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BOSTON MA 02111-2621

IAB/JMS 25669-014 CIP CON

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MS: PATENT APPLICATION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Serial No. TBA File No. 25669-014 CIP CON By: IAB/JMS **F**Title: CHARACTERIZATION OF AN ANTIBIOTIC IMPREGNATED...Application of Mario Abdenmour et al. Date: March 29, 2004

The U.S. PTO Mail Room acknowledges receipt of the following on the date stamped hereon:

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|--|--|
| <input type="checkbox"/> Req. for CPA under 37 CFR 1.53(d) | <input type="checkbox"/> Provisional Application Cover Sheet |
| <input type="checkbox"/> Change of Attorney's Address | <input checked="" type="checkbox"/> Inf. Discl. Statement, PTO Form 1449 (3 pgs) |
| <input type="checkbox"/> New Power of Attorney | <input type="checkbox"/> References Cited |
| <input checked="" type="checkbox"/> Patent Application | <input type="checkbox"/> Copy of Notice to File Missing Parts |
| <input checked="" type="checkbox"/> Non-provisional <input type="checkbox"/> Provisional | <input type="checkbox"/> Amendment/Response |
| Incl. <u>25</u> pages, (<u>21</u> pgs) Specification, | <input type="checkbox"/> Petition for Ext. of Time (x2) |
| (<u>1</u> pgs) Abstract, (<u>3</u> pgs) Claims (<u>26</u> # claims) | <input type="checkbox"/> Issue Fee Transmittal |
| <input type="checkbox"/> Design Patent Application | <input type="checkbox"/> Letter to Official Draftsperson |
| <input checked="" type="checkbox"/> Declaration(s) (<u>copy, signed, 3</u> crrpts) | <input type="checkbox"/> Notice of Appeal |
| <input checked="" type="checkbox"/> Drawings <u>10</u> sheet(s) (FIGS. <u>1-10</u>) | <input type="checkbox"/> Brief (x3) |
| <input checked="" type="checkbox"/> Formal <input type="checkbox"/> Informal | <input checked="" type="checkbox"/> Check for \$557.00 Check # 18367 |
| <input type="checkbox"/> Verified Statement claiming small entity status | <input checked="" type="checkbox"/> Transmittal Letter (x2) |
| <input type="checkbox"/> Assignment and Cover Sheet | <input type="checkbox"/> Cert. of Mailing under 37 CFR 1.8(a) |
| | <input checked="" type="checkbox"/> Express Mail Label No. EV328182377US |

☒ Other Revocation by Assignee and New Power of Attorney (copy,
11 pgs) 22856 U.S. PTO
10/812638

DATE MAILED March 29, 2004

032904